



Ashcraft & Gerel, LLP

Attorneys & Counsellors at Law

Established in 1953

Lee C. Ashcraft 1908 – 1993 | Martin E. Gerel 1918 – 2011

December 16, 2020

Hon. Joel A. Pisano (Ret.)
Walsh Pizzi O'Reilly Falanga LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102

**RE: *In Re: Johnson & Johnson Talcum Powder Products Marketing,
Sales Practices and Products Liability Litigation (MDL No. 2738)***

**Plaintiff's Steering Committee Request for MDL Liability
Depositions**

Dear Judge Pisano:

As you are aware, Chief Judge Wolfson's *Daubert* ruling was issued on April 27, 2020. Subsequent to that ruling, at the May 6, 2020 Status Conference, Chief Judge Wolfson directed the PSC to notify Counsel for the Johnson & Johnson ("J&J") Defendants which corporate fact witnesses it wished to depose in the MDL. On August 7, 2020, the PSC informed Counsel that it wished to depose three J&J corporate fact witnesses as well as take several 30(b)(6) depositions on four specific liability issues.¹ Importantly, none of the witnesses requested by the PSC for deposition have been previously deposed in a talc-ovarian cancer case, state or federal. In a response letter dated September 22, 2020, Counsel for J&J informed

¹ See Letter from PSC to Susan Sharko, Esq, August 6, 2020 [Exhibit 1]. These witnesses are Michael Chudkowski, PhD, JiJo Janes, MD and Helen Han Hsu. In addition, the PSC requested four (4) depositions under Rule 30(b)(6) including witnesses on Risk and Mitigation Policies, Procedures and Committees for cosmetic products, Marketing and Advertising and Sales. For a further description of these witnesses, see *infra* at page 5.

Hon. Judge Pisano (Ret.)

December 16, 2020

Page 2

the PSC that J&J declined to produce any of the requested witnesses.² At the November 17, 2020 Status Conference, the parties raised this issue to Chief Judge Wolfson and were directed to bring it to you for resolution.³

As an initial matter, it should be noted that the PSC's request for MDL liability depositions at this juncture is timely. In January 2018, the PSC initially requested the opportunity to depose these and other J&J employees.⁴ J&J opposed the PSC's request because the Court had bifurcated these proceedings, deciding to consider *Daubert* challenges related to general causation first.⁵ In its February 16, 2020 Order, this Court agreed that J&J corporate fact witness testimony was not necessary "at this [general causation] stage" (emphasis added).⁶ However, in so finding, Chief Judge Wolfson noted that the PSC may be entitled to obtain testimony from J&J corporate witnesses if the case "eventually moves" from *Daubert* proceedings and "into fact discovery."⁷ As the Court noted, "We will cross that bridge when we come to it."

We are now at that bridge. This MDL has now moved from the general causation phase to the liability discovery and case-specific causation phase. Even though general causation legal issues have been resolved, J&J continues to resist PSC's request to question its employees under oath about their conduct relating to talc and ovarian cancer over the decades. J&J asserts that taking testimony from its corporate fact witnesses at this time in this federal ovarian cancer MDL is duplicative and unduly burdensome, stating that: 1) it has produced other witnesses in individual state court cases, mostly in mesothelioma cases where ovarian cancer was not even

² See Letter from Susan Sharko to PSC, September 22, 2020 [Exhibit 2].

³ In addition to the six J&J depositions that the PSC requested in the MDL, the PSC informed the Court of its intent to cross-notice J&J corporate depositions that are being scheduled in state court proceedings. The PSC may also preserve 3rd party testimony for use at trial and for use in remanded cases. See Status Conference Report (Doc. 15681) at Section II, p. 2-3 [Exhibit 3].

⁴ PSC Preliminary Disclosure of Potential Deponents (January 10, 2018) [Exhibit 4].

⁵ Order, February 6, 2018 (Doc. 4173) [Exhibit 5].

⁶ *Id.* at p. 1-2.

⁷ *Id.* at p. 3, n3.

Hon. Judge Pisano (Ret.)
December 16, 2020
Page 3

an issue and before it made a full document production; and 2) it is burdensome and duplicative because it has now produced “over 2 million pages of documents.”

To be blunt, J&J’s “burdensome” and “duplicative” objections are nothing more than an effort to prevent the PSC from presenting to the jury the damning story of J&J’s decade’s long indifference to women who used Johnson’s talcum powder products for feminine hygiene. Through J&J’s own witnesses, the PSC will show that J&J marketed Johnson’s Baby Powder and Shower-to-Shower products as safe and pure despite knowing for decades that these iconic products may pose a deadly safety hazard to women.

Contrary to any suggestion made by J&J, it is undisputed that:

- **None** of the liability testimony sought from the requested J&J corporate witnesses could have been set in this MDL before the Court’s *Daubert* ruling because of the Court’s discovery bifurcation Order. Therefore, the requested depositions are **timely**.
- **None** of the requested J&J corporate witnesses have been deposed in a state or federal ovarian cancer case (or mesothelioma case). Therefore, the requested depositions are **not** duplicative.
- **None** of the requested J&J corporate witness deposition will interfere with the timing of any MDL Bellwether trial or any remand of any federal case. Therefore, the requested depositions are **not** burdensome.
- The vast majority of all of the J&J corporate witness depositions, that have been taken outside of this MDL, were taken in talc-induced **mesothelioma cases** where J&J’s knowledge of, and actions, regarding talc-induced **ovarian cancer** was **not** an issue. Therefore, the requested depositions are **not** cumulative.
- The vast majority of the state court J&J corporate witness depositions that have been taken outside this MDL occurred **before** 2018, when J&J had produced only about 25% of the documents it has since produced in this MDL. Therefore, new subject matter exists.

Hon. Judge Pisano (Ret.)
December 16, 2020
Page 4

For the reasons outlined above, and as set forth below in more detail, J&J should be required to produce the requested corporate witnesses for deposition in the MDL.⁸

1. **The Court's Bifurcation Order Prohibited the PSC from Taking Testimony On Important Liability Questions Before April 2020.**

As the Court noted in its February 6, 2018 Order: "In previous case management conferences, the [Chief Judge Wolfson] has called for staging of discovery with the initial focus on the area of general causation."⁹ The Court further noted, the PSC has "not established a need [for them] *at this stage*."¹⁰

As a consequence of that bifurcation, the PSC was prohibited from taking testimony from any of the thirty (30) J&J corporate fact witnesses that it initially sought. Rather, the PSC was permitted to take only 30(b)(6) testimony from J&J witnesses "limited to [4] subjects" which "may be necessary, prior to completion of plaintiffs' causation expert reports."¹¹ As defined by the February 6th Order, the four (4) discrete 30(b)(6) categories relating to general causation included: "1) composition of the products; 2) testing of the products by the defendants; 3) sampling of the products by defendants; and 4) any influence or bias in the published literature caused by Defendants."¹²

⁸ The PSC is aware of various corporate fact depositions that are being scheduled and conducted in various state courts in St. Louis, Missouri and Broward County, Florida. These depositions are being scheduled in the first half of 2021. In an effort to further streamline discovery, the PSC will cross-notice these depositions in this MDL.

⁹ See, recommendation and Order Feb. 6, 2018 (Doc. 4173) (Pisano, J) ("Feb. 6 Order") [Exhibit 5]; The list of the 30 J&J witnesses is in the pleading entitled **THE PLAINTIFF STEERING COMMITTEE'S INITIAL DISCLOSURE POTENTIAL DEPONENTS** (January 10, 2018) [Exhibit 4]

¹⁰ Feb. 6, 2018 Order at p. 4 (emphasis added).

¹¹ *Id.* at p. 3-4.

¹² *Id.*

Hon. Judge Pisano (Ret.)

December 16, 2020

Page 5

Notably, J&J was adamant that the PSC be prevented from taking any testimony of any individual J&J corporate employees on any key liability question. As a result, the PSC was prevented from taking the testimony of any individual J&J corporate fact witness on the following topics relevant to J&J's liability:

- The knowledge of J&J executives about the potential risk of *ovarian cancer* with this ubiquitous cosmetic product and when they specifically knew of that potential risk;¹³
- The options available at different times to mitigate the potential risk of ovarian cancer, including warnings and instructions to women about the genital use of talcum powder products and the availability of safer alternative formulations like cornstarch;
- J&J's marketing of this iconic product for decades to consumers as safe and pure;
- J&J's communications over the years with regulatory and *quasi*-regulatory bodies about the potential risks of ovarian cancer and the availability of risk mitigation measures;
- J&J's collusion with other talc manufacturers to prevent any warnings to consumers regarding the risks of cosmetic talc use;
- J&J's decision not to reformulate its talcum powder products with cornstarch; and
- J&J's failure to conduct its own studies regarding the safety of its talcum powder products.

In limiting the PSC to only 30(b)(6) witnesses on specifically identified topics in the first stage of these bifurcated proceedings, the Court was cognizant that additional fact testimony from J&J employees might be important later in the second stage.¹⁴ Thus, while scientific admissions by J&J employees were off-the table

¹³ Unlike a pharmaceutical drug, the FDA cannot not require that the manufacturer of a cosmetic submit labeling before the product is marketed. Cosmetics do not have to undergo review or approval before marketing and safety information need not be submitted by the manufacturer. See <https://www.fda.gov/cosmetics/cosmetic-ingredients/talc>. The duty to ensure safety is wholly the responsibility of the manufacturer [https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated].

¹⁴ Feb. 6 Order, n.3 [Exhibit 5].

Hon. Judge Pisano (Ret.)
December 16, 2020
Page 6

during the *Daubert* phase of these bifurcated proceedings, the Court recognized that such testimony would be important if the case were to proceed to a jury trial on the merits. As Chief Judge Wolfson explained when recommending against the taking of J&J corporate fact witness depositions in the *Daubert* phase of this case:

“I understand why you think that [admissions on the state of the science by individual J&J employees] will bolster your case---if you believe that there are admissions. But that does not go to what your own experts will be opining upon based on their own review of what the science was at the time and over these years in this area regardless of whether they admit it or not. *That’s great for trial, to put that before a jury: Look they admitted there was a problem here. I understand that.* But for your experts to opine, they have to independently and their opinions stand on their own as to what they are relying on for the science.”¹⁵

2. **None of the PSC’s Requested Witnesses Have Testified in any Talc Case, State or Federal.**

a) **The Fact Witnesses: Chudkowski, James and Han Hsu:**

It is undisputed that no plaintiff in any talc case (state or federal, ovarian cancer or mesothelioma) has ever taken the deposition of Chudkowski, Han Hsu or James. A brief summary of the relevance and importance of these three witnesses is as follows:

- **Michael Chudkowski, PhD** was J&J’s Director of Product Safety until 2001, a timeframe when plaintiffs believe that consumers should have been protected from the potential risks of talcum powder. He has never been deposed. Plaintiffs believe he has knowledge of critical decision making regarding emerging evidence of talc-associated ovarian cancer and how J&J reacted to that evidence. Despite his involvement, J&J claims that “there is nothing to be gained,” because he would have to recall events “that took place twenty or more years ago.”¹⁶ Plaintiffs are entitled to test his memory of these decisions.

¹⁵ See Status Conference Transcript (Doc. 3667), p. 20:11-25 (emphasis added) [Exhibit 6].

¹⁶ Exhibit 2, p. 3.

Hon. Judge Pisano (Ret.)

December 16, 2020

Page 7

- **Jijo James, MD** was JJCI's Chief Medical Officer in charge of Johnson's Baby Powder through 2017. J&J contends it does not have to produce him since it previously produced his subordinate, Susan Nicholson, MD, as a witness. He has never been deposed. Plaintiffs are entitled to elicit evidence from the superior (Dr. James) and not the subordinate (Dr. Nicholson) on issues known to him.
- **Helen Han Hsu, PhD** was a Vice President and Head of Drug Safety Sciences at JJCI. In that capacity, she coordinated J&J's response to the National Toxicology Program (NTP), a quasi-regulatory agency. Though the NTP had initially voted to list talc as a carcinogen in the early 2000's, Helen Han Hsu was instrumental in derailing that listing. She has never been deposed. Plaintiffs are entitled to question her on what transpired and led to NTP's ultimate decision.

b) 30(b)(6) Witnesses on Risk Assessment and Mitigation Policies, Marketing and Sales:

Nor have any of the requested 30(b)(6) depositions been taken in any ovarian cancer case, state or federal. The subject matters upon which Plaintiffs expect them to testify are:

- **Policies and Procedures for Risk Assessment and Risk Mitigation:** While J&J contends that it has produced witnesses to testify to the "state of the science" during the *Daubert* phase, there is no question that it has **not** produced testimony as to what its policies and procedures were and what its safety committees did (or did not do) to assess risk and take measures to protect the public from the potential risk of cancer.
- **30(b)(6) Witnesses on Marketing:** Johnson's talcum powder products were iconic products that were marketed to consumers, and in particular women, as pure and safe. While J&J contends that "colleagues" in a mesothelioma case took such a deposition, it is undisputed that no plaintiff in **any** ovarian cancer case (state or federal) has taken such testimony from a J&J witness for use in an ovarian cancer trial.

Hon. Judge Pisano (Ret.)

December 16, 2020

Page 8

- **30(b)(6) Witnesses on Sales:** It is undisputed that no J&J witness has previously testified on sales.

3. **The J&J Witness Requested Testimony is Not Duplicative since None of the Witnesses have been Deposed in any Other Ovarian Cancer Case, State or Federal, and the Subject Matter will be Liability Not General Causation.**

J&J contends that the testimony plaintiffs seek in the post-*Daubert* phase are duplicative.

The *causation* question, however—whether talcum powder products can cause ovarian cancer—is just one element of what the PSC must prove. The PSC must also establish that J&J is *liable* for a plaintiff’s injuries. Central to that *liability* question is when J&J became aware that its talcum powder products may be associated with the risk of ovarian cancer, whether there were mitigation steps that J&J failed to take in the face of those potential risks, and whether J&J misled consumers about the safety and purity of its talc. J&J conflates what Plaintiffs must show for general causation with what it can show to demonstrate liability under negligence, strict liability, and punitive damage laws. In making its *liability* claims, it is important to emphasize that Plaintiffs’ liability burden of proof is not coexistent with their burden to establish causation. For example, the Food Drug and Cosmetic Act makes clear that a cosmetic manufacturer must provide consumers with warnings and instructions when there is a potential risk of harm even before causation is established. Thus, for example, CFR § 740.1(a), regarding the **Establishment of Warning Statements** for Cosmetics, provides that:

The label of a cosmetic product *shall bear a warning* whenever necessary or appropriate to prevent a *health hazard that may be associated* with the product. (Emphasis Added).

The parties’ exclusive focus on the general causation question in the *Daubert* phase of these bifurcated MDL proceedings forced the parties to focus solely and exclusively on whether causation can be **established as of today**. In other words, the focus was not when ovarian cancer (a “health hazard”) “may” have been “associated” with its talcum powders such that J&J should have taken steps to prevent it. The testimony that the PSC now seeks is intended to create that record, i.e., to support the Plaintiffs’ claims that it was “appropriate and necessary” to take

Hon. Judge Pisano (Ret.)
December 16, 2020
Page 9

action decades before 2020 because it was known decades ago that ovarian cancer “may be associated with the product.”

While J&J’s opposition to the PSC’s 30(b)(6) depositions on risk assessment and mitigation committees and policies is predicted on the suggestion that these areas were covered by the PSC’s 30(b)(6) depositions of Dr. John Hopkins (designated on talc testing methods) and Dr. Susan Nicholson (designated on bias in studies), even a cursory examination of their depositions reveal that they were not. In this regard, it is notable that neither were even employed by J&J between 1999 – 2015, the timeframe when the evidence of ovarian cancer risk was mounting. Dr. Hopkins left J&J’s employment in 1999. Dr. Nicholson did not have professional responsibilities related to Johnson’s Baby Powder until 2015.¹⁷ Moreover, the words “ovarian cancer” was mentioned only 7 times in the 2 days of Dr. Hopkin’s deposition and only 81 times in Dr. Nicholson’s 2 days of testimony while the terms “safety Committee.” “Policies” or” SOP” appeared a total of 3 times in their combined 4 days of testimony.

4. The Fact that J&J Recently Produced “over 2 million pages of documents” Should Not Preclude the PSC from Taking Testimony of the Requested J&J Witnesses.

J&J further resists the PSC’s taking of corporate witness depositions because it has now produced “more than 2 million pages of documents.”

Initially, it is axiomatic that the Federal Rules of Civil Procedure permit parties to take testimony from a party from whom documents are produced. Just as a plaintiff cannot prevent J&J from taking her deposition because she has produced volumes of medical, financial and other records, J&J cannot prevent the plaintiff from deposing witnesses about the documents it has produced. Both testimony and documents are important components of a jury trial.

Moreover, and as Your Honor is well aware, the total number of pages produced by J&J in the state court ovarian cancer cases and in this MDL has only recently become “more than 2 million pages.” Until April 2017, J&J’s document production in ovarian cancer cases stood at 500,000 pages – only a quarter of what

¹⁷ See T. 3443-3444, *Daniels v. Johnson & Johnson, et al.*, Cause No. 1422-CC09326-01, Cir. Court of City of St. Louis, Missouri (Feb. 24, 2017) [Exhibit 7].

Hon. Judge Pisano (Ret.)
December 16, 2020
Page 10

has now been produced in 2020,¹⁸ Only after this Court entered CMO 9 in September 2017 and held a conference in October 2017 did J&J produce the bulk of its documents in earnest. It is believed that the vast majority of state court corporate depositions upon which J&J relies occurred before 2017, prior to J&J's production of approximately 75% of the documents now produced in the MDL.

J&J's argument liability depositions should not proceed because the company has produced documents in nonsensical and unavailing.

5. The Depositions Sought By The PSC Can Be Accomplished Before a MDL Bellwether Trial.

At this time, no bellwether case has been selected and no date has been set for the first Bellwether trial. Indeed, case-specific discovery has only just begun.

There is more than adequate time for the parties to complete these J&J corporate witness depositions in this MDL and, if the parties cooperate in scheduling, there should be no undue burden on any party in completing these depositions in the first half of 2021.

CONCLUSION

The PSC respectfully requests that it be permitted to take the liability depositions of J&J witnesses that are the subject of this letter during the first half of 2021.

Respectfully submitted,

/s/ Michelle A. Parfitt
Michelle A. Parfitt

/s/ P. Leigh O'Dell
P. Leigh O'Dell

cc: Hon. Freda L. Wolfson, Chief Judge (via ECF and Courtesy Copy)
All counsel of record (via ECF)

¹⁸ See Plaintiffs' Steering Committee's Initial Disclosure of Potential Deponents (Jan. 10, 2018) [Exhibit 4].